DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Cortex Manufacturing, Inc.
% Mr. Andrew Jones
Director
421 South Davies Road
LAKE STEVENS WA 98258

March 26, 2015

Re: K142294
Trade/Device Name: FlexiMarc
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: March 14, 2015
Received: March 18, 2015

Dear Mr. Jones:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142294

Device Name
FlexiMarc

Indications for Use *(Describe)*
In situations where the location of specific anatomy, normal and diseased needs to be marked for future procedures this device will serve as a surrogate locator. The all gold FlexiMarc is placed either in advance or during a treatment procedure. These all gold FlexiMarcs can be visualized using medical imaging devices and they provide a reference from which the treatment can be guided.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Special 510(k) Summary for FlexiMarc

Cortex Manufacturing Inc.
621 SR 9 NE
PMB-B8
Lake Stevens, WA 98258

Contact: Andrew Jones
Phone: (425) 334 - 2277

Preparation date: March 15, 2015

Trade Name: FlexiMarc (K142294)
Common Name: Implanted Marker
Classification Name: 892.5050

Predicate Device: K100267

Additional Reference Device: RadioMed, Visicoil (K031206 and K070305)

Device Description:

FlexiMarc is an implanted marker used to identify the location of normal or diseased tissue for future treatments. The marker is placed at or near the treatment site and can easily be visualized in subsequent imaging studies. The location of the treatment area is then identified with respect to the marker.

The FlexiMarc soft tissue marker is fabricated of all biocompatible pure gold. It will be available in varying lengths from 3 MM to 4 CM overall and will range in diameter from 0.35 MM to 1.6 MM. It will be available in single and multi-node formats. These are detailed in the table below. FlexiMarc is delivered in sterile preexisting needles ranging from 25 GA to 14 GA, solo in a sterile pouch, or in non-sterile bulk.

Description	FlexiMarc K100267	Desired Range (K142284)
Diameter (range)	0.50 – 1.60 MM	0.35 – 1.60 MM

Number of Nodes	Node Length	Diameter Range
1	3 – 10 MM	0.35 – 1.60 MM
2	3 MM (10 MM O.C. Spacing)	0.90 -1.60 MM
3	3 MM (10 MM O.C. Spacing)	0.90 -1.60 MM
4	3 MM (10 MM O.C. Spacing)	0.90 -1.60 MM
5	3 MM (10 MM O.C. Spacing)	0.90 -1.60 MM

FlexiMarc is intended for single use and is permanently implanted in the body. They are available pre-sterilized in accordance with FDA QSR sterilization procedures.

Intended Use Statement with Additional Use Data

In situations where the location of specific anatomy, normal and diseased needs to be marked for future procedures this device will serve as a surrogate locator. The all gold FlexiMarc is placed either in advance or during a treatment procedure. These all gold FlexiMarcs can be visualized using medical imaging devices and they provide a reference from which the treatment can be guided.

Technological Comparison to Predicate Device

The predicate device has a diameter range from 0.50 to 1.6 MM the new specification would increase the range to 0.35 to 1.6 MM. This is the only modification; otherwise all other technical aspects are identical including but not exclusive to:

- Indication for use
- Materiel used to manufacture
- Packaging
- Sterility process

Clinical Performance Comparison

The markers have been imaged using the typical imaging devices including, CT, CBCT, kV x-ray and MV x-ray, both markers are visible in all of these modalities. It is noted that Gold Markers under 0.40 MM in diameter may not be visible with all MV x-ray imaging systems.

There is a substantial body of published work indicating that smaller diameter markers down to 0.35 MM do not pose an increased risk in marker migration. In these studies markers were placed in live participants in the torso region of the body specifically including the GI tract and pancreas. In these studies several markers in the 0.35 MM diameter range were implanted. The distances between the markers were compared overtime and the migration patterns found were not significantly different to that of the larger diameter markers.

Conclusion

The markers have identical material, irregular surface and are deployed into the body using the same techniques. They are packaged and sterilized in the same fashion. There is no change to the safety and effectiveness when comparing the new smaller marker size with the existing predicate device.